



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

Rec'd 3/26/98 jfb

MAR 13 1998

Mr. Henry P. Cheatham III
Nature's Bounty
90 Orville Drive
Bohemia, New York 11716-2510

Dear Mr. Cheatham:

This is in response to your letter of January 19, 1996 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Nature's Bounty is making the following claims, among other claims, for the product:

ECHINACEA (*Echinacea purpurea*)

"Many Native American tribes have used Echinacea, or purple coneflower, for centuries. The Cheyenne and Comanche gathered this plant for use during cold seasons. It quickly won the favor of early European settlers and has now become a well-loved herb both here and abroad. Scientific research studies on Echinacea abound, documenting its ability to help maintain overall health and well-being.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to prevent, treat or mitigate a disease, namely the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation

975-0163

LET 141

Page 2 - Mr. Henry P. Cheatham III

under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New York District Office, Office of Compliance, HFR-NE100

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456;jel:3/13/98:docname:naturesb.adv:disc26



90 Orville Drive, Bohemia, NY 11716-2510 Phone: (516) 567-9500 Fax: (516) 244-2136

January 19, 1996


Dr. Linda Kahl, Ph.D.
Office of Special Nutritionals
Center For Food Safety and Applied Nutrition
Food & Drug Administration
200 C Street SW HFS-455
Washington DC 20204

Dear Dr. Kahl:

This letter is written pursuant to current legislative guidelines (DSHEA) requiring FDA notification of structure and function claims for nutrition supplements.

Nature's Bounty manufactures and sells a line of concentrated herbal extracts. For your files, the attachments present the specific package copy containing structure and function claim material pertaining to these products.

Sincerely,


Henry P. Cheatham III
Director

HPC/tei

attachments

44160
44161



90 Orville Drive, Bohemia, NY 11716-2510 Phone: (516) 567-9500 Fax: (516) 244-2136

DONG QUAI ROOT (*Angelica sinensis*)

Women first harvested Dong Quai root over 5,000 years ago to use as a natural aid for balancing their systems. Because of its established reputation for promoting women's health and well-being, this Chinese root is often considered to be like ginseng for women.

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

CHINESE RED GINSENG ROOT (*Panax ginseng*)

Nature's Bounty Chinese Red Ginseng is made from hand-harvested, carefully trimmed, premium quality roots. Used daily by millions of people in the Orient, Ginseng is now desired internationally by such vigorous people as high-powered executives and competitive athletes.

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

ECHINACEA (*Echinacea purpurea*)

Many Native American tribes have used Echinacea, or purple coneflower, for centuries. The Cheyenne and Comanche gathered this plant for use during cold seasons. It quickly won the favor of early European settlers and has now become a well-loved herb both here and abroad. Scientific research studies on Echinacea abound, documenting its ability to help maintain overall health and well-being.

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

SAW PALMETTO EXTRACT (*Serenoa repens*)

The berries of the saw palmetto palm were used centuries ago by Native Americans and are safe enough to eat. These berries produce a special extract which is the leading herb for men's health, used specifically for men who are in their later years.

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.